

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

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| Applicant's or agent's file reference 00010-007WO1 | FOR FURTHER ACTION | See item 4 below |
| International application No. PCT/US2008/071090 | International filing date (<i>day/month/year</i>) 25 July 2008 (25.07.2008) | Priority date (<i>day/month/year</i>) 26 July 2007 (26.07.2007) |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 | | |
| Applicant CALIFORNIA PACIFIC MEDICAL CENTER | | |

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|-------------------------------------|---|---|-----------|---------------------|--------------------------|------------|----------|-------------------------------------|-------------|--|--------------------------|------------|----------------------------|-------------------------------------|-----------|---|--------------------------|------------|-------------------------|--------------------------|-------------|--|--------------------------|--------------|---|
| 1. | This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a). | | | | | | | | | | | | | | | | | | | | | | | | |
| 2. | This REPORT consists of a total of 5 sheets, including this cover sheet. In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead. | | | | | | | | | | | | | | | | | | | | | | | | |
| 3. | <p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 60%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> | <input checked="" type="checkbox"/> | Box No. I | Basis of the report | <input type="checkbox"/> | Box No. II | Priority | <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | <input type="checkbox"/> | Box No. IV | Lack of unity of invention | <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | <input type="checkbox"/> | Box No. VI | Certain documents cited | <input type="checkbox"/> | Box No. VII | Certain defects in the international application | <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. II | Priority | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VI | Certain documents cited | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application | | | | | | | | | | | | | | | | | | | | | | | |
| 4. | The International Bureau will communicate this report to designated Offices in accordance with Rules 44 <i>bis</i> .3(c) and 93 <i>bis</i> .1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44 <i>bis</i> .2). | | | | | | | | | | | | | | | | | | | | | | | | |

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|---|---|---|--|---------------------------|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70 | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Date of issuance of this report 26 January 2010 (26.01.2010)</td> </tr> <tr> <td style="padding: 5px;">Authorized officer <div style="text-align: center; font-weight: bold;">Philippe Becamel</div></td> </tr> <tr> <td style="padding: 5px;">e-mail: pt12.pct@wipo.int</td> </tr> </table> | Date of issuance of this report 26 January 2010 (26.01.2010) | Authorized officer <div style="text-align: center; font-weight: bold;">Philippe Becamel</div> | e-mail: pt12.pct@wipo.int |
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| e-mail: pt12.pct@wipo.int | | | | |

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

BAKER, Jr., Joseph R.

Gavrilovich, Dodd & Lindsey LLP 4445 Eastgate Mall, Suite
200 San Diego California 92121 USA

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **02 DECEMBER 2008 (02.12.2008)**

Applicant's or agent's file reference
00010-007WO1

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US2008/071090

International filing date (day/month/year)

25 JULY 2008 (25.07.2008)

Priority date(day/month/year)

26 JULY 2007 (26.07.2007)

International Patent Classification (IPC) or both national classification and IPC

C12M 1/40(2006.01)i, C12Q 1/58(2006.01)i

Applicant

CALIFORNIA PACIFIC MEDICAL CENTER et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
Government Complex-Daejeon, 139
Seonsa-ro, Seo-gu, Daejeon 302
-701, Republic of Korea
Facsimile No. 82-42-472-7140



Date of completion of this opinion
02 DECEMBER 2008 (02.12.2008)

Authorized officer

JEONG, JAE CHEOL

Telephone No.82-42-481-8385



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2008/071090

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of :
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☒ on paper
 - ☒ in electronic form
 - c. time of filing/furnishing
 - ☒ contained in the international application as filed.
 - ☒ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2008/071090

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 1-45

because:

☒ the said international application, or the said claims Nos. 1-44

relate to the following subject matter which does not require an international search (*specify*):

The subject matter of claims 1-44 does not require an opinion with respect to industrial applicability as it is directed to a diagnostic method (Rules 43 bis.1(b), Rule 67.1(iv)).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 19, 22, 45

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2008/071090

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|--------|-----|
| Novelty (N) | Claims | None | YES |
| | Claims | 46, 47 | NO |
| Inventive step (IS) | Claims | None | YES |
| | Claims | 46, 47 | NO |
| Industrial applicability (IA) | Claims | 46, 47 | YES |
| | Claims | None | NO |

2. Citations and explanations :

Reference is made to the following documents:

D1: US 20050014165 A1 (LEE, N.M.) 20 January 2005

D2: US 6423491 B1 (HOWE, J.R.) 23 July 2002

The present invention relates to a kit for determination of a gastrointestinal disease or disorder by carrying out detection of a FSHH biomarker panel, a polyp biomarker panel, a senser biomarker panel, a rectal bleeding biomarker panel or any combination thereof.

D1 provides a panel of biomarkers and a kit for analysis of colorectal cancer and colorectal polyps. The panel has been used to assess changes in human tissue from surgical and biopsy samples against normal human control panel of biomarkers.

D2 shows the identification of the gene responsible for familial juvenile polyposis. Defects in this gene are associated with a predisposition to gastrointestinal cancers.

Novelty & Inventive Step (PCT Article 33(2) & 33(3))

D1, which is considered to be the closest state of the art to claims 46 and 47 of the present application, discloses a kit and a panel of biomarkers for analysis of colorectal cancer and colorectal polyps and the panel of D1 has been used to assess changes in human tissue from surgical and biopsy samples against normal human control panel of biomarkers. Accordingly, D1 is the same as claims 46 and 47 of the present application in the constitution of the invention. Therefore, claims 46 and 47 do not meet the requirements of novelty and inventive step set forth in PCT Article 33(2) and 33(3).

Industrial Applicability

Claims 46 and 47 meet the requirements for industrial applicability in PCT Article 33(4).